BIOPSY GRID

BACKGROUND OF THE INVENTION

Marking grids are used during medical imaging procedures to provide visual reference points on the resulting image. The marking grid contains a contrast agent that is visible on images produced by the imaging technology employed, for example, X-rays, computerized tomography (CT) scans and/or magnetic resonance imaging (MRI). Marking grids can be used to locate the position of internal structures in the body of a patient, such as abnormal tissues or tumors, relative to the reference marks on the image. In use, the marking grid is attached to the external surface or skin of a patient's body, and the patient and marking grid are exposed to imaging radiation. The contrast agent in the marking grid produces dots, lines, or other shapes on the image that can be used as reference points.

Marking grids are useful for locating the position on the surface of a patient where a biopsy needle should be inserted. The grids typically include a radiopaque material, arranged in strips, mounted on a radio translucent border or frame. The grids are typically placed on the skin of the patient and a cross section of the grid is visible on a CT scan. The technician can determine a position for insertion of a needle by viewing the grid pattern, visible on the CT scan at the patient's skin as a series of dots representing a cross section of the strips, and inserting the needle in the appropriate location relative to the grid pattern. However, one issue with prior marking grids is that the strips on the grids often blocked access to the appropriate location on the patients skin, requiring that the marking grid be moved in order to mark the location with a skin marker prior to inserting the biopsy needle.

The present invention provides a biopsy grid in which each individual reference strip can be easily removed by the medical technician without having to move the grid, which allows for precise positioning of the biopsy needle on the surface of the patient. The present invention also provides an improved manufacturing method for making marking grids, and improved materials for use in the radio-opaque strip material.

The following references may be relevant to the present disclosure: U.S. Pat. Nos. 7,086,172; 6,714,628; 6,356,621; 5,285,785; 5,052,035; 4,985,019; 3,547,121.

BRIEF SUMMARY OF THE INVENTION

Embodiments herein provide compositions and methods useful in identifying the location of a marker relative to a tissue of interest in medical images. In one aspect, the invention provides a grid that is useful in performing biopsy procedures. In some embodiments, the grid is adapted to be arranged on a patient's skin to provide positioning information in a medical imaging procedure. In one embodiment, the grid comprises a) a frame comprising a top and bottom surface; b) a hydrogel layer attached to the top of the frame and having a top and bottom surface and comprising a mixture of a hydrogel and a contrast agent; and c) an adhesive layer on the bottom surface of the frame. The adhesive may be a low tack, releasable adhesive, and is used to attach the grid to a patient during imaging. A release liner may be provided on the bottom of the adhesive, and may be removed just prior to attaching the grid to a patient. The grid includes reference lines formed by the hydrogel layer.

In some embodiments, the grid comprises a contrast agent that is selected from a radiopaque material or a material visible in a magnetic resonance image.

In some embodiments, the grid further has a top sheet contacted to a top surface of the hydrogel layer. The top sheet is provided on the top surface of the hydrogel layer to reduce the possibility of the hydrogel drying during shipping and storage. The top sheet covers the hydrogel, and is removed, for example by a tab, just prior to use of the grid.

In some embodiments, the frame comprises a support material selected from polyester, polypropylene, polyethylene, nylon, paper or other suitable radio translucent and rigid or semi-rigid materials. The composition of the hydrogel may provide sufficient tack for the hydrogel to stick directly to the frame. In some embodiments, to aid in adhesion of the hydrogel to the frame, the top surface of the support frame is coated with an adhesive for attaching the hydrogel to the frame.

In some embodiments, the silicone release liner further comprises a pull tab.

In some embodiments, the grid has a feature on one side (e.g., the left hand side) that distinguishes that side from other sides during imaging.

In another aspect, embodiments herein provide a method of imaging a tissue of interest in a subject. For example, in some embodiments, the method comprises positioning the biopsy grid described above to the external surface or skin of the subject external to the tissue of interest; and observing the location of the biopsy grid markers relative to the tissue of interest by at least one of X-ray, CT scan, mammography, or MRI. In some embodiments, the biopsy grid is affixed to the skin of the subject by the adhesive layer. In some embodiments, the subject is an animal or human subject.

In another aspect, the invention provides a method of manufacturing a biopsy grid. In some embodiments, the manufacturing method comprises the steps of a) combining at least one contrast agent with a hydrogel to form a mixture, b) contacting the hydrogel mixture with a carrier sheet, c) curing the hydrogel mixture on a carrier sheet, d) attaching the hydrogel and carrier sheet to a frame, and e) cutting the hydrogel to a grid pattern. An adhesive layer may then be provided on the bottom of the frame, and a silicone-coated release liner may be placed over the adhesive.

DEFINITIONS

The term "hydrogel" refers to a gel comprising a network of polymer chains that are water-insoluble, in which water is the dispersion medium.

The term "release liner" refers to a layer, in embodiments comprising silicone coated polyethylene, that may be used to releasably cover the adhesive layer of the grid, and protects the adhesive layer and the exposed hydrogel from drying prior to use. The silicone release liner is typically removed from the adhesive layer prior to application of the grid to the skin of the subject undergoing an imaging procedure.

The term "adhesive layer" refers to a layer comprising a non-toxic medical grade adhesive that is suitable for affixing the grid to the skin of a subject. In some embodiments, the adhesive layer is made of acrylic.

The term "contrast agent" refers to a radiopaque substance used in radiography to enhance the contrast of an image. Non-limiting examples of radiopaque materials include a metal such as tungsten or similar metal powder, a metallic salt such as barium sulfate or calcium carbonate, a halogen such as iodine, or any other suitable radiopaque material. Non-limiting examples of contrast agents suitable for MRI include a paramagnetic material, a fatty oil such as mineral oil, vegetable oil, or fish oil, or other suitable materials and combinations thereof. As examples, the paramagnetic material may be ferric chloride, ferric ammonium citrate, gadolinium or an